

REMARKS

In the Office Action, claims 1, 5-14, 17-21, 23-27, 29, 30 and 32-37 are rejected under 35 U.S.C. § 103. Applicants believe that the obviousness rejections are improper at least for the reasons set forth below.

In the Office Action, claims 1, 5-14, 17-21, 23-27, 29, 30, 32-34, 36 and 37 are rejected under 35 U.S.C. § 103 in view of WO 99/24145 and U.S. Patent No. 5,469,145 (Johnson). The Patent Office has primarily relied on WO 99/24145 and thus has relied on Johnson to remedy the deficiencies of same. Applicants believe that this rejection should be withdrawn.

Of the pending claims at issue, claims 1, 11, 17, 27, 30, and 36 are the sole independent claims at issue. Claim 1 recites an apparatus for detecting dislodgement of a needle inserted into a patient. The apparatus includes a sensor capable of detecting wetness due to blood; and a sensor holder adapted to secure the sensor in juxtaposition to the needle such that the sensor detects wetness due to blood loss from the patient upon dislodgement of the needle. Claim 1 further recites that the sensor includes a capacitive sensor.

Claim 11 recites an apparatus for detecting needle dislodgement during hemodialysis. The apparatus includes a sensor holder having a cavity; and a capacitive sensor including an electrode enclosed within the cavity of the sensor holder such that the capacitive sensor is capable of detecting wetness from blood due to needle dislodgement during hemodialysis wherein the capacitive sensor does not contact blood upon detection thereof.

Claim 17 recites an apparatus for controlling blood loss from the patient during hemodialysis. The apparatus includes a sensor that is capable of detecting wetness due to blood and a sensor holder that is adapted to secure the sensor to the patient such that the sensor produces a signal indicative of wetness due to blood loss from the patient upon dislodgement of a venous needle inserted into the patient. The apparatus further includes a controller capable of processing the signal to prevent blood flow through the venous needle such that blood loss from the patient due to dislodgement of the venous needle is minimized.

Claim 27 recites a method of detecting needle dislodgement. The method includes providing a sensor capable of detecting wetness due to blood wherein the sensor includes a capacitive sensor; inserting a needle into a patient; and securing the sensor to the patient such that the sensor detects blood on the patient upon dislodgement of the needle.

Claim 30 recites a method of controlling blood loss from a patient due to needle dislodgement. The method includes providing a sensor capable of detecting wetness due to blood wherein the sensor includes a capacitive sensor; inserting a needle into the patient; securing the sensor to the patient such that the sensor produces a signal indicative of wetness due to blood loss from the patient upon dislodgement of the needle; and processing the signal to prevent blood flow through the venous needle such that blood loss from the patient due to needle dislodgement is minimized.

Claim 36 recites a method of providing dialysis to a patient. The method includes providing a sensor capable of detecting wetness due to blood wherein the sensor includes a capacitive sensor that does not contact blood upon detection thereof; inserting a venous needle into the patient; securing the sensor in juxtaposition to the venous needle; passing blood through the venous needle via a hemodialysis machine; and detecting blood loss from the patient upon dislodgement of the venous needle.

In general, the present invention includes a sensor that is capable of detecting wetness due to blood and a sensor holder that can be adapted to secure the sensor to a patient such that needle dislodgment can be effectively detected during treatment or therapy. During hemodialysis, for example, dislodgement of a venous needle can occur. If dislodged, a significant amount of blood loss can occur within a relatively short period of time. In this regard, the present invention can detect wetness due to blood loss from the patient resulting from the dislodged needle. The detection of blood loss is an indication that the needle has become dislodged. Thus, needle dislodgement can be detected. See, Specification, page 7, lines 8-17.

Applicants have found that the present invention can detect blood loss due to needle dislodgement with high sensitivity and selectivity such that responsive measures can be taken to minimize blood loss due to needle dislodgement. The ability to act responsively and quickly to minimize blood loss upon detection thereof is particularly important with respect to needle dislodgement during hemodialysis. If not detected and responded to immediately, the amount of blood loss can be significant as previously discussed. The present invention is capable of taking active or responsive measures (i.e., shut-off blood pump, activate venous line clamp and/or the like) to minimize blood loss. See, Specification, page 14, lines 1-10.

Even if combinable, WO 99/24145 and Johnson are distinguishable from the claimed invention. At the outset, the primary WO 99/24145 reference merely relates to a resistive-type

sensor as even the Patent Office appears to admits. Clearly, this contrasts the claimed invention that requires, in part, a capacitive sensor.

Further, nowhere does this reference disclose or suggest the sensor holder as claimed. In WO 99/24145, an adhesive patch 40 or wrap-around cuff-like member 50 are provided where the needle can be inserted through a slot 52 and into the patient as illustrated in Figures 2 and 3. See also, WO 99/24145, page 8. In contrast, the sensor holder as claimed can act to shield and protect the sensor, needle and other components that it covers in addition to properly positioning and securing the sensor over the access or insertion region of the needle as further supported in the specification on page 8 at lines 5-8.

For example, the sensor holder can include a pad configuration as further defined in claim 18 and illustrated, for example, in Figure 1 and the corresponding text of the Specification on pages 7 and 8. Indeed, claim 11 requires, in part, a sensor holder that includes a cavity within which the capacitive sensor is enclosed such that the capacitive sensor does not contact blood upon detection thereof as further illustrated, for example, in Figs. 3A-3C and the corresponding text of the Specification on pages 10 to 12. Therefore, Applicants believe that WO 99/24145 is distinguishable from the claimed invention based on at least these reasons as discussed above.

With respect to Johnson, Applicants question whether Johnson and WO 99/24145 can be combined in the first place. The Federal Circuit has held:

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys. Inc., 157 F.3d 1340, 1352* (Fed. Cir. 1998) (describing “teaching or suggestion or motivation [to combine]” as “an essential evidentiary component of an obviousness holding”); *In re Rouffet, 149 F.3d 1350, 1359* (Fed. Cir. 1998) (“the Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”).*** The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. *In re Dembiczak, 175 F.3d 994, 999* (Fed. Cir. 1999).

In *Dembiczak*, the Federal Circuit reversed the Patent Office’s obviousness rejection of a utility patent for an orange trash bag with jack-o’-lantern features. The prior art contained: (1) references “teaching the construction of decorated [jack-o’-lantern] paper bags” and (2)

conventional trash bags. Id. At 1000. The Patent Office “simply stated that ‘the [paper bag] references would have suggested the application of...facial indicia to the prior art plastic trash bag.’” Id. But, “[n]owhere does the [Patent Office] particularly identify any suggestion, teaching, or motivation to combine the children’s art references...with the conventional trash...bag references.” Id. Accordingly, the Patent Office’s “conclusion of obviousness, as a matter of law, cannot stand.” Id.

In the present case, the Patent Office attempts to apply teachings from diaper technology (Johnson) to a medical device for extracorporeal circuits, such as for hemodialysis (WO 99/24145). More specifically, Johnson provides a capacitive-type sensor that can purportedly detect diaper wetness where WO 99/24145 provides a fluid-sensing device for purportedly detecting whether a fistula needle connects a patient to an extracorporeal blood circuit of a dialysis machine (See, WO 99/24145, Abstract). The Patent Office alleges that the motivation to combine can be found in Johnson, “namely to provide a sensor that is cheap and reusable.” See, Office Action, page 2.

Like *Dembiczak*, the Patent Office in this case has failed to establish a clear and particular showing that a motivation to combine WO 99/24145 and Johnson exists. At the outset, it is not clear that one skilled in the art would be motivated to use a “cheap and reusable sensor” for diaper wetness detection and apply it to needle separation or dislodgment detection for extracorporeal circuits, such as during hemodialysis. Indeed, a potentially life-threatening situation can occur if the venous fistula needle should accidentally become separated from the patient body during dialysis treatment. See, WO 99/24145, page 2, lines 5-7. If not detected and responded to immediately, the amount of blood loss can be significant as previously discussed. This suggests a higher degree of detection sensitivity that is required for needle separation detection, particularly during hemodialysis or other like medical therapies, as compared to diaper wetness detection.

Why then would one skilled in the art be motivated to apply the teachings of diaper wetness detection to needle separation or dislodgment detection where such a difference in detection sensitivity requirements exists? Clearly, this degree of difference in detection sensitivity between diaper wetness detection and needle separation detection is much greater than the degree of difference between orange-colored paper bags and conventional trash bags as considered in *Dembiczak* where, as in this case, the Patent Office did not particularly identify

any suggestion, teaching, or motivation to combine the references. Again, nowhere do either WO 99/24145 or Johnson provide that a capacitive-type sensor can be applied for detecting the presence of blood, let alone detecting the separation of the needle from the patient, such as during hemodialysis. Indeed, WO 99/24145 effectively teaches away from a capacitive-type sensor for such purpose of needle separation detection where this reference relates to a resistive-type sensor as discussed above. Moreover, the Patent Office alleges that the motivation to combine can be found in a sensor that is “cheap and reusable” as previously discussed. Of course, “conclusory statements of generalized advantages and convenient assumptions about skill artisans...are inadequate to support a finding of motivation...” *In re Beasley*, 2004 WL 2793170, *5 (Fed. Cir. Dec. 7, 2004). Therefore, Applicants believe that the Patent Office has improperly combined WO 99/24145 and Johnson for at least these reasons.

Even if combinable, Johnson cannot be relied on solely to remedy the deficiencies of WO 99/24145. For example, the alleged holder (122) in Johnson merely relates to an adhesive patch that is applied to a front surface of a diaper 111. See, Johnson, col. 8, lines 58-61. Clearly, this contrasts the sensor holder as claimed that can act to shield and protect the sensor, needle and other components that it covers in addition to properly positioning and securing the sensor over the access or insertion region of the needle as previously discussed.

Further, the alleged holder (122) in Johnson does not provide a cavity where the rear surface 117 of the housing 114 includes a pair of electrical conductors 119 and 121 that are in contact with the front side 113 of the diaper 110 (See, Johnson, col. 8, lines 48-53; and Fig. 10) contrary to the Patent Office’s position. This also contrasts the claimed invention that requires, in part, a sensor holder with a cavity within which the capacitive sensor is enclosed as further defined in claim 11 and discussed above. Moreover, the electrode pair in Johnson contrasts claim 12 that further requires a single plate electrode. What the Patent Office has done is to apply hindsight reasoning in support of the obviousness rejection. Of course this is improper. Therefore, Applicants respectfully submit that the cited art, even if combinable, fails to render obvious the claimed invention based on at least these reasons.

Accordingly, Applicants respectfully request that the obviousness rejection in view of WO 99/24145 and Johnson be withdrawn.

In the Office Action, claim 35 is rejected under 35 U.S.C. § 103 as allegedly unpatentable over WO 99/24145 in view of Johnson and further in view of WO 97/10013,

Shintani et al #4181610 or JP 104233. Claim 35 depends indirectly from independent claim 30. Therefore, Applicants believe that WO 99/24145 and Johnson, even if properly combinable, are distinguishable from claim 35 for substantially the same reasons as discussed above and as applied to claim 30.

Further, the remaining cited art cannot be relied on solely to remedy the deficiencies of WO 99/24145 and Johnson. Indeed, the remaining cited art are merely relied on for their alleged teachings regarding closing a control valve in response to blood leakage. See, Office Action, page 4. Therefore, even if properly combinable, the cited references fail to render obvious the claimed invention as defined in claim 35.

Accordingly, Applicants respectfully request that the obviousness rejection of claim 35 be withdrawn.

In the Office Action, claims 1, 5-7 and 10 are rejected under 35 U.S.C. §103 in view of U.S. Patent No. 5,579,765 (Cox) and Johnson. At the outset, Cox is clearly distinguishable from the claimed invention where Cox fails to provide a capacitive type sensor as even admitted by the Patent Office. See, Office Action, pages 4 and 5. Further, the primary focus of Cox relates to the detection of external bleeding from a puncture site on a patient. See, Cox, Abstract. Nowhere does Cox disclose or suggest the detection of needle dislodgment. In contrast, independent claim 1 recites an apparatus for detecting dislodgment of a needle inserted into a patient. Claims 5-7 and 10 depend from claim 1 either directly or indirectly. Therefore, Cox on its own is different from the claimed invention at least for these reasons.

Further, Applicants question the combinability of Cox and Johnson for similar reasons as discussed above where Johnson relates to diaper wetness detection and Cox relates to detecting external bleeding from a puncture site. Even if properly combinable, Johnson cannot be relied on solely to remedy the deficiencies of Cox. Indeed, Johnson merely relates to diaper wetness detection as previously discussed. Again, Cox merely relates to detecting external bleeding from a puncture site. Nowhere is it disclosed or suggested that needle dislodgment can be detected in contrast to the apparatus for detecting dislodgment of a needle inserted into a patient as claimed and discussed above. Clearly, the Patent Office has improperly relied on hindsight reasoning in support of the obviousness rejection. Therefore, Cox and Johnson, even if combinable, fail to render obvious the claimed invention for at least these reasons.

In the Office Action, claims 8, 9, 11-14, 17-21, and 23-26 are rejected under 35 U.S.C. §103 as allegedly unpatentable over Cox in view of Johnson and further in view of WO 99/24145. Of the pending claims at issue, claims 11 and 17 are independent claims where claims 8 and 9 depend from claim 1 and the remaining claims depend from claims 11 or 17. Claim 1 recites an apparatus for detecting needle dislodgment that includes, in part, a capacitive sensor and a sensor holder adapted to secure the sensor in juxtaposition to the needle; Claim 11 recites an apparatus for detecting needle dislodgment that includes, in part, a capacitive sensor and a sensor holder with a cavity wherein the sensor is enclosed; and claim 17 recites an apparatus for controlling blood loss from a patient during hemodialysis that includes, in part, a capacitive sensor capable of detecting wetness due to blood and a sensor holder adapted to secure the sensor to the patient such that blood loss from the patient due to dislodgment of the venous needle can be minimized. In contrast, Cox merely relates to the detection of external bleeding from a puncture site as previously discussed. Moreover, Cox fails to provide a capacitive sensor as even admitted by the Patent Office and discussed above.

Further, Johnson and WO 99/24145 cannot be relied on solely to remedy the deficiencies of Cox. At the outset, Applicants question whether Cox and Johnson can be properly combined with WO 99/24145 in the first place for substantially the same reasons as discussed above. What the Patent Office has done is rely improperly on hindsight reasoning. Again, Johnson merely relates to diaper wetness detection where Cox merely relates to the detection of bleeding from a puncture site. Indeed, nowhere is the detection of needle dislodgment disclosed or suggested. Moreover, WO 99/24145 effectively teaches away from capacitive sensors and the detection of needle dislodgment, such as for controlling blood loss due to same during hemodialysis, as required by the claimed invention and as previously discussed.

Even if properly combinable, the cited references are distinguishable from the claimed invention. Indeed, the Patent Office merely relies on WO 99/24145 for its alleged teaching regarding the use of a blood leakage detector in a hemodialysis machine. See, Office Action, page 5. Moreover, the alleged holder (122) in Johnson is substantially different from the claimed sensor holder, such as a sensor holder with a cavity for enclosing the capacitive sensor as required by claim 11 and discussed above. The sensor is a single plate electrode as further required by claim 12. Based on at least these reasons, Cox, Johnson and WO 99/24145, even if combinable, fail to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejection in view of Cox, Johnson and WO 99/24145 be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY 

Robert M. Barrett
Reg. No. 30,142
P.O. Box 1135
Chicago, Illinois 60690-1135
Phone: (312) 807-4204

Dated: January 4, 2005